5. 510(K) SUMMARY

MAY 1 5 2013

510(k) number: k120615

Date Prepared: 15 April 2013

Submitter:	Alere San Diego, Inc.	**Contact:**	Edward Brehm
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Trade name: Alere Cholestech LDX® Lipid Profile•GLU Cassette Alere Cholestech LDX® Analyzer	**Common Name (Device Type):** Alere Cholestech LDX® Lipid Profile•GLU Cassette Alere Cholestech LDX® Analyzer

Glucose:	
Class:	II
Regulation number:	21 CFR 862.1345
Product Code:	CGA
Panel:	Clinical Chemistry
Lipids:	
Class:	I (meets limitation for exemption per 21 CFR 862.9(c)(4) and (9)
Regulation number:	21 CFR 862.1175, 862.1475, 862.1705
Product Code(s):	CHH, LBS, JGY
Panel:	Clinical Chemistry
Analyzer:	
Class:	I (exempt)
Regulation number:	21 CFR 862.2160
Product Code:	JJE
Panel:	Clinical Chemistry

Original 510(k) Submissions:	**Clearance Date:**
K901900 – LDX Lipid Monitoring System	July 24, 1990
K932727 – Lipid Profile•GLU Cassette	Nov 9, 1993

5.1. Intended Use / Indications for Use:

The Alere Cholestech LDX® System is a small, portable analyzer and test cassette system. The System is for in vitro diagnostic use only. The Lipid Profile•GLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Alere Cholestech LDX® Analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

5.2. Summary of Changes:

The revision of the software is being changed from revision v3.30 to v3.41, which incorporates a humidity sensor as part of the ROM pack. This sensor measures the ambient humidity and applies a small correction factor from a lookup table to the result from the assay algorithm.

5.3. Substantial Equivalence:

Version v3.41 of the Alere Cholestech LDX® Analyzer ROM pack software is substantially equivalent to Alere Cholestech LDX® Analyzer ROM pack software version v3.30. The change is invisible to the user. Analytical results when the analyzer is operated between 40% and 60% relative humidity are unchanged and no correction factor is required. In more extreme cases, when the ambient humidity is between 20% RH and 40% RH, or between 60% RH and 80%RH, a small correction factor is applied.

5.4. List of Similarities:

The Intended use is unchanged
The Indications for use is unchanged
The analytical performance has been returned to its original intent
The manufacturing process is unchanged

5.5. List of Differences:

Software version v3.41 contains a humidity sensor which measures the ambient humidity and applies a small correction factor to the analytical results based on a lookup table.

5.6. Conclusion:

Performance testing demonstrates that the software upgrade from revision v3.30 to v3.41 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

Alere San Diego, Inc.
C/O Edward Brehm, Ph.D.
9975 Summers Ridge Road
SAN DIEGO CA 92121

Re: K120615
Trade/Device Name: Alere Cholestech LDX® Lipid Profile • GLU Cassette
Alere Cholestech LDX® Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, CHH, LBS, JGY, JJE
Dated: May 10, 2013
Received: May 13, 2013

Dear Dr. Brehm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120615

Device Name: Alere Cholestech LDX® Analyzer
Alere Cholestech LDX® Lipid Profile•GLU Cassette

Intended Use / Indications for Use:
The Alere Cholestech LDX® System is a small, portable analyzer and test cassette system. The System is for in vitro diagnostic use only. The Lipid Profile•GLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Alere Cholestech LDX® Analyzer.

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Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k120615